

REMARKS

Applicants' Representative thanks Examiner R. Cook for the helpful and courteous discussion of January 16, 2002.

Claims 17-32 are pending.

Upon entry of this amendment, claims 17-33 will be pending. Claim 33 has been added. No new matter has been added.

I. The Request For Clarification Of Continuing Data

The Office has requested that Applicants clarify the continuing data (Office Action, page 2, 1st paragraph). Applicants have not claimed the benefit of the filing date of U.S. Patent Application No. 08/869,426 (now U.S. Patent No. 6,194,440). Applicants draw the Office's attention to the Preliminary Amendment filed on June 14, 2001, amending the specification to claim priority only to parent U.S. Patent Application No. 09/089,377. Applicants submit that the continuing data is thus clarified.

II. The Rejections Under The First Paragraph Of 35 U.S.C. § 112

Claims 17-32 stand rejected under § 112, first paragraph, as lacking "support in the specification for attaching the ester or amide substituent at any atom in the heterocyclic compound" other than at the C-2 position (Office Action, page 2, 3rd paragraph).

Applicants respectfully traverse. The claims are part of the specification and can provide written description support. Accordingly, the subject matter of claim 17 is supported

by claim 17 as originally filed. Applicants submit that the rejection is improper and should be withdrawn.

Claim 17 stands rejected under § 112, first paragraph, as non-enabled by the specification. The Office asserts that the specification is only enabled for compounds having affinity for FKBP-type immunophilins, noting that the specification at page 12 discloses that the compounds of the claimed compositions have an affinity for FKBP-type immunophilin (Office Action, page 2, 4th paragraph).

Applicants respectfully traverse.

The Office has not provided any basis for concluding that it would require undue experimentation to make or use the present invention. The present invention as claimed in claim 17 is a pharmaceutical composition as defined therein. The specification at page 12 describes one of the properties of the compounds included in the compositions, i.e., they have an affinity for FKBP-type immunophilins. The Office has not shown how this property of these compounds relates to the level of experimentation required to make and use the compositions. If the Office is asserting that certain compounds within the scope of claim 17 do not have an affinity for FKBP-type immunophilins and are therefore inoperative, the Office has not satisfied its burden to provide a reasonable basis to support such a conclusion. M.P.E.P. § 2164.07.I.B. (8th Ed., August 2001). Applicants therefore request that the Office withdraw the non-enablement rejection.

III. The Provisos In The Claims

The Office has requested that Applicants cite considerations used in drafting the provisos in the claims (Office Action, page 2, lines 4-5 from the bottom).

The proviso in claim 17 was drafted in consideration of U.S. Patent Nos. 5,846,979; 6,054,452; and 6,251,892 and U.S. Patent Application Nos. 09/842,174 (filed April 26, 2001) and 09/134,474 (filed August 14, 1998).

IV. The Rejection Of The Claims For Non-Statutory Double Patenting

Claims 17-32 stand provisionally rejected for non-statutory double patenting over claims 5, 6, and 8 of co-pending U.S. Patent Application No. 09/784,174 (Office Action, page 3, 3rd paragraph from the bottom). The Office asserts that the claims are “not patentably distinct from each other because the instant claims reads [sic] on the claims of ‘174 when J and K in ‘174 form a heterocyclic ring” (Id.).

Applicants respectfully traverse. Mere overlap of subject matter does not establish a lack of patentable distinction. The rejection is thus improper and should be withdrawn.

V. The Request For Identification Of Related Cases

The Office requested that Applicants identify related cases (Office Action, page 3, last paragraph). Applicants have filed concurrently herewith an Information Disclosure Statement listing related pending applications and issued patents. The items listed on page 1 of the attached Forms PTO-1449 have been submitted separately.

VI. References Cited But Not Received By The Office

The Office noted that certain references cited in a previously-filed Information Disclosure Statement were not considered by the Office because the references were not received (Office Action, page 4, first paragraph). Applicants have listed the references on a separate Form 1449 for the Examiner's convenience, and have submitted those missing references separately.

VII. CONCLUSION


Applicant submits that the pending claims are now in condition for allowance. If the Office has questions, the Office is invited to call Applicants' Representative directly at (202) 974-6018.

Please charge or credit Deposit Account No. 12-2475 for all fees as needed.

Respectfully submitted,

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